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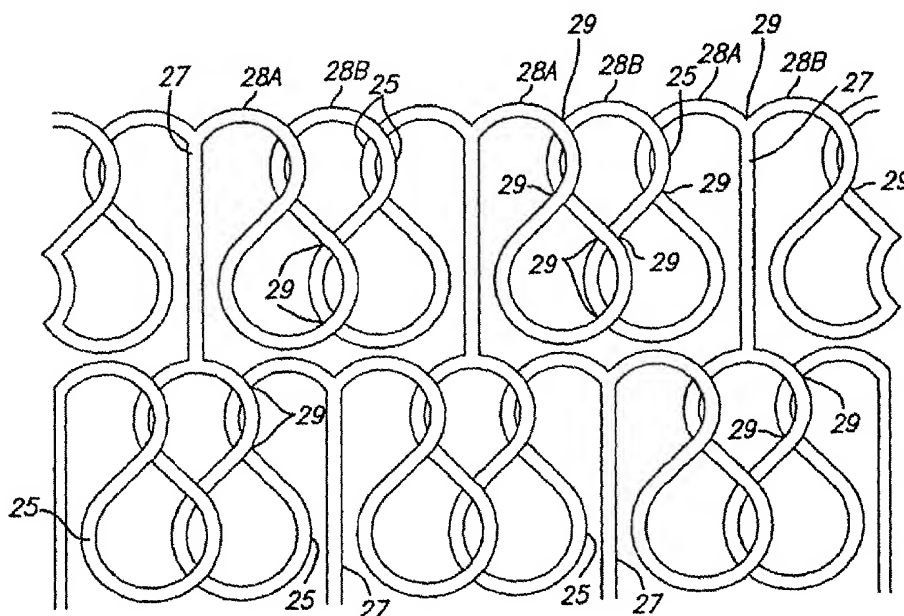
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(54) Title: STENT HAVING OVERLAPPING STRUTS



(57) Abstract: An intravascular stent having a pattern of overlapping struts. The overlapping struts allow the stent to be crimped to a smaller initial delivery diameter than may be achieved with non-overlapping designs for given metal density. The present invention stent has a reduced delivery diameter which allows for the construction of reduced profile stent-delivery systems, which thereby allow for the successful stenting of smaller vessels than has heretofore been possible.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

STENT HAVING OVERLAPPING STRUTS

BACKGROUND OF THE INVENTION

The present invention relates generally to endoprosthesis devices, which are commonly referred to as stents, and more particularly pertains to improvements thereto that provide for a reduced delivery profile, increased vessel scaffolding and in the case of balloon expandable stents, improved stent security.

Stents are generally thin walled tubular-shaped devices composed of complex patterns of interconnecting struts which function to hold open a segment of a blood vessel or other body lumen such as a coronary artery. They also are suitable for supporting a dissected arterial lining or intimal flap that can occlude a vessel lumen. There are two general classes of stents, balloon expandable stents and spring-like self-expandable stents. Balloon expandable stents are delivered within a vessel lumen by means of a dilatation catheter and are plastically deformed by means of an expandable member, such as an inflation balloon, from a small initial diameter to a larger expanded diameter. Self-expanding stents by contrast are formed as spring elements which are radially compressible about a delivery catheter. A compressed self-expanding stent is typically held in the compressed state by a delivery sheath. Upon delivery to a lesion site, the delivery sheath is retracted allowing the stent to expand.

Either type of stent has advantages and disadvantages. One disadvantage of self expanding stents with respect to balloon expandable stents is the relatively large profile of the self-expanding stent-delivery system. Because, self-expanding stents typically are restrained during delivery by a sheath, the outside diameter of a self-expanding stent-delivery system is greater than that of a comparable balloon expandable stent-delivery system which does not require a delivery sheath. As such, balloon expandable stents may be delivered within smaller vessels than can now be reached with a self-expanding stent.

One disadvantage of balloon expandable stents is the tendency for the stent to slip on the inflation balloon. Balloon expandable stents are typically crimped onto an inflation balloon in such a manner as to provide for a uniform crimp of the stent

about the balloon. Typically, such crimps adequately secure the stent to the balloon. However, in certain circumstances, such as when the stent encounters obstacles such as hardened plaque or a flap of tissue partially torn from a vessel wall, stents occasionally slide off of the delivery catheter. It is believed that this slippage problem occurs because the stent forms a smooth continuous interface with the balloon and may not always generate sufficient frictional resistance to remain positioned on the balloon when encountering obstacles within the patient's vasculature. One approach to solving the slippage problem is to protect the balloon expandable stent with a delivery sheath. However, the use of a delivery sheath negates the reduced profile advantage of balloon expandable stent-delivery systems with respect to self-expanding stent-delivery systems.

Both balloon expandable and self-expandable stents must be able to simultaneously satisfy a number of interrelated mechanical requirements. First, the stent must exhibit sufficient radial or hoop strength in its expanded state to withstand the structural loads, namely radially compressive forces, imposed on the stent by the walls of a vessel. It is advantageous to distribute such loads over as much of the stent as possible and over as much lumen wall as possible. Uniform loading minimizes the possibility of localized crippling of the stent which may induce a general structural failure. In addition, uniform loading tends to minimize injury to the vessel wall. Second, it is desirable for a stent to provide a high degree of scaffolding of the lumen walls, i.e., minimize the gaps between stent struts, in order to prevent prolapse of plaque between the struts and into the lumen. Third, a stent should be sufficiently radiopaque to be readily visible by fluoroscopy procedures. Radiopacity with typical stent materials such as stainless steel and nickel-titanium alloy is generally a function of the stent's mass, and is in particular a function of the thickness of the stent struts. Fourth, a stent should be longitudinally flexible in order to be delivered through tortuous vessels. Finally, a stent should have a small crimped or initial delivery diameter in order to facilitate advancement through small vessels and must be able to expand to a second larger diameter for implantation within a body lumen. Generally,

5 area of the scaffolding as well as aid in neo-intimal formation after placement. Further, the two (stents and grafts) are often designed into one device called a stent-graft.

Each year about half a million Americans suffer a stroke in which obstruction or hemorrhage impairs the crucial flow of blood to the brain. About 150,000 of these stroke victims die, making stroke the third leading cause of death after heart disease and cancer, and
10 many more suffer permanent disability. According to the American Heart Association the cost of treating stroke exceeds \$25 billion a year.

Currently, approximately 180,000 Americans undergo a preventative operation to clear carotid arteries that carry blood to the brain. The operation, known as Carotid Endarterectomy (surgical removal of plaque from the carotid artery), usually requires patients
15 to stay in the hospital a few days, with typically a few weeks recovery time. This surgical procedure is increasing at an annual rate of greater than 20%.

A debate has arisen between vascular surgeons and "interventional" cardiologists and radiologists concerning the advantages of using of stents and/or stent-grafts to treat occluded carotid arteries compared with surgery. Stroke prevention operations/surgeries like
20 endarterectomies are performed by vascular surgeons in the United States at a cost of about \$1.5 billion per year. Efforts to use small stents in the brain to open and maintain patency in clogged arteries have triggered a fierce debate comparing the safety and efficacy of the medical techniques. Interventionalists claim that the scaffolding accomplished with stents is easier on the patient and the patient's pocketbook. Surgeons, on the other hand, are skeptical
25 of stenting in the carotid because of the potential for neurological complications as well as the potential for the stent to 'recoil' (return to a smaller diameter than when originally placed) some time after initial placement.

Various strategies have been devised and developed for vascular intervention in the treatment of Chronic Occlusive Disease (COD). Much of the critical occlusive disease
30 occurs at junctions (bifurcations) in the vasculature. Of particular interest are occluded carotid arteries and other bifurcated vasculature junctures.

A recent study funded by the NIH indicates the incidence of stroke can be reduced by 55% if the occluded carotid is treated by surgical intervention. This surgical procedure

SUMMARY OF THE INVENTION

The present invention provides a stent which may be crimped to a smaller delivery diameter than previously known stent devices for a given metal density. In addition, the stent may positively engage the material of an inflation balloon, in a manner previously thought undesirable in the art, and thereby improve stent security on the balloon. The stent achieves these results while continuing to fulfill all of the mechanical and structural requirements attendant to its function as a stent.

The stent of the present invention can take many forms and preferably is configured to form a tubular member having a lattice structure of struts. The stent has a smaller delivery diameter in which it is preferably mounted on a catheter, and an expanded diameter wherein it is implanted in a body lumen, such as a coronary artery. When the stent is in the smaller delivery diameter, at least some of the struts overlap so that the stent has a very small profile, increased gripping force on the catheter, and is able to achieve a larger expanded diameter. The struts can overlap circumferentially or along the longitudinal axis of the stent, or both.

In one embodiment, the stent of the present invention includes generally a plurality of cylindrical rings that are interconnected by a plurality of links. When viewed in isolation, each cylindrical ring is generally formed as a pattern of alternating U-shaped portions which may be thought of as comprising a plurality of peaks and valleys, where a peak represents the apex of the U-shaped portion and a valley represents the space between the struts which form the open end of the U. The stent's advantages are achieved by circumferentially offsetting the valleys of each cylindrical ring from those of adjacent cylindrical rings and by nesting the rings such that the peaks of each adjacent cylindrical ring are centered midway within the valleys of each preceding ring. The U-shaped portions are formed from struts which are configured with an angled step midway along their length. The angled step essentially divides each strut into an upper portion and a lower portion. Thus, when the stent is crimped or compressed to its initial delivery diameter, the lower portion of each strut slides underneath the upper portion of each strut in a preceding nested ring. Thus, when

compressed, the stent forms a pattern of nested cylindrical rings with overlapping struts. The overlapping struts allow the stent to be crimped to an initial delivery diameter smaller than that of prior art non-overlapping strut designs for a given metal density. Therefore, the profiles of both balloon expandable and self-expandable stent-
5 delivery systems may be reduced with the present invention stent. Reduced delivery system profiles allow smaller vessels to be treated with the present invention stent than can be reached with prior art stents. In addition, in balloon expandable embodiments of the stent, the overlapping strut configuration allows the struts to engage or pinch the balloon material, thereby increasing stent security on the balloon.

10 Each of the cylindrical rings making up the stent has a proximal end and a distal end and a cylindrical plane defined by a cylindrical outer wall surface that extends circumferentially between the proximal end and the distal end of the cylindrical ring. The cylindrical rings are interconnected by at least one longitudinal connecting link which attaches one cylindrical ring to an adjacent cylindrical ring. In addition,
15 each connecting link may be circumferentially offset from the previous connecting link in a preceding ring. Circumferentially offsetting the links increases the longitudinal flexibility of the stent. The connecting links are positioned substantially within the cylindrical plane of the outer wall surface of the cylindrical rings.

Each connecting link is about one half the length of the struts which form
20 each U-shaped portion. The connecting links are positioned so that they are within the curved part of a U-shaped portion and connect the apex of one U-shaped portion to the apex of a preceding U-shaped portion, positioning the preceding U-shaped portion about half way within the valley of the succeeding U-shaped portion. Typically, balloon expandable embodiments of the stent may be formed from a plastically
25 deformable metal alloy such as stainless steel and similar materials. Self-expanding embodiments may be formed from shape memory alloys or superelastic alloys which expand upon undergoing a martensite to austenite phase change. Such a phase change is typically initiated by increasing the temperature of the alloy above a predetermined transition temperature, or in the case of alloys which exhibit stress induced martensite

FIG. 6 is a perspective view of the stent of FIG. 1, shown in the as-machined state where the struts are closely spaced but not overlapping.

FIG. 7 is a perspective view of the stent of FIG. 1, shown in an expanded state.

5 FIG. 8 is an enlarged top plan view of one of the U-shaped portions which form the cylindrical rings of the stent of the present invention.

FIG. 9 is a side view of the U-shaped portion of FIG. 7.

FIG. 10 is a plan view of a flattened section of one embodiment of the stent of the present invention, shown in the as machined state where the struts are
10 closely spaced but not overlapping.

FIG. 11A is a plan view of a flattened section of one embodiment of the stent of the present invention where the struts are overlapping in the delivery diameter configuration.

FIG. 11B is the stent of FIG. 11A in the expanded configuration where
15 the struts are not overlapping.

FIG. 12A is a plan view of a flattened section of one embodiment of the stent of the present invention where the struts are overlapping in the delivery diameter configuration.

FIG. 12B is the stent of FIG. 12A in the expanded configuration where
20 the struts are not overlapping.

FIG. 13A is a plan view of a flattened section of one embodiment of the stent of the present invention where the struts are overlapping in the delivery diameter configuration.

FIG. 13B is the stent of FIG. 13A in the expanded configuration where
25 the struts are not overlapping.

FIG. 14A is a plan view of a flattened section of one embodiment of the stent of the present invention where the struts are overlapping in the delivery diameter configuration.

FIG. 14B is the stent of FIG. 14A in the expanded configuration where the struts are not overlapping.

FIG. 15A is a plan view of a flattened section of one embodiment of the stent of the present invention where the struts are overlapping in the delivery diameter
5 configuration.

FIG. 15B is the stent of FIG. 15A in the expanded configuration where the struts are not overlapping.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 The present invention stent improves on existing stents by providing a stent having a unique pattern with novel overlapping struts. The overlapping struts allow the stent to be crimped to a smaller delivery diameter than may be achieved with prior art stents. The present invention stent's reduced delivery diameter allows for the construction of reduced profile stent-delivery systems, which thereby allow for the
15 successful stenting of smaller vessels than has heretofore been possible.

Referring now to FIG. 1, the stent 10 of the present invention is shown mounted on a catheter 12 of the known rapid exchange configuration and having a lumen 14 and an inflation member 16. The stent and catheter are shown inside a lumen 22 of an arterial vessel 24. The stent is shown positioned across a small amount of
20 arterial plaque 23 adhering to the lumen of the artery. The plaque is the remainder of an arterial lesion which has been previously dilated or radially compressed against the walls of the artery or has been partially removed from the artery. Lesion dilation is typically accomplished by an angioplasty procedure, while lesion removal is typically accomplished by an atherectomy procedure. These and other procedures for the
25 treatment of arterial lesions are well known to those skilled in the art.

With most lesion treatment procedures, the treated artery suffers a degree of trauma and in a certain percentage of cases may abruptly collapse or may slowly narrow over a period of time. To prevent either of these conditions, the treated artery is often fitted with a prosthetic device, such as the stent 10 of the present invention. The

stent provides radial support for the treated vessel and thereby prevents collapse of the lumen 24 and further provides scaffolding to prevent plaque prolapse within the lumen. The stent may also be used to repair an arterial dissection, or an intimal flap, both of which are commonly found in the coronary arteries, peripheral arteries and other vessels. A low profile stent is desirable for the above mentioned treatments because a low profile stent may be more easily delivered to a lesion site, may be delivered to lesions within small vessels, and is less likely abrade a lumen wall during delivery. Abrasion of lumen walls may cause particles of plaque or other material deposited within the lumen to break free from the lumen wall and migrate with the flow of blood as an embolic particle. Embolic particles may later lodge within a small blood vessel leading to full or partial occlusion of the vessel with adverse consequences to the patient.

With continued reference to FIG. 1, in a typical stent placement procedure, a guiding catheter (not shown) is percutaneously introduced into the cardiovascular system of a patient through the femoral arteries by means of a conventional Seldinger technique and advanced within a patient's vascular system until the distal end of the guiding catheter is positioned at a point proximal to the lesion site. A guide wire 20 and the stent- delivery catheter 12, are enclosed within a delivery sheath 26 (for use with a self-expanding stent), and are introduced through the guiding catheter with the guide wire sliding within the stent-delivery catheter. The guide wire is first advanced out of the guiding catheter into the arterial vessel 22 and is directed across the arterial lesion. The stent-delivery catheter and protective sheath are subsequently advanced over the previously advanced guide wire until the stent is properly positioned across the lesion.

Referring now to FIG. 2, once in position, the delivery sheath 26 (for use with a self-expanding stent) is withdrawn proximally and the dilation balloon 16 is inflated to a predetermined size to radially expand the stent 10 against the inside of the artery wall and thereby implant the stent within the lumen 24 of the artery. The balloon is then deflated to a small profile so that the stent- delivery catheter may be withdrawn from the patient's vasculature and blood flow resumed through the artery.

Since the stent 10 typically is formed from an elongated tubular member (it may be formed flat and rolled into a cylinder or tube), the rings and links of the stent are relatively flat in transverse cross-section, thus after implantation into the artery 22 as shown in FIG. 3, minimal interference with blood flow occurs. Eventually the stent
5 becomes covered with endothelial cell growth which further minimizes blood flow interference. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in placing stents.

In one embodiment, as shown in FIGS. 4A and 4B, the stent 10 has a number of curved struts 25 and straight struts 27. There are numerous stent patterns that
10 are well known and that have both curved and straight struts arranged in various patterns. Thus, FIGS. 4A and 4B are merely representative of a strut pattern that has curved and straight struts. The invention, however, applies to any combination of all curved, all straight, or curved and straight patterns. As shown in FIG. 4A, in the smaller delivery diameter, the curved struts are overlapping at multiple points 29. The
15 overlapping points 29 create an inner diameter portion 28A and an outer diameter portion 28B. As shown in FIG. 4B, when the stent is expanded to the expanded implanted diameter, the curved struts 25 are no longer overlapping with each other. Again, not all of the curved or straight struts overlap, and the number and positioning of the overlaps may vary with specific applications. FIGS. 4A and 4B depict a flattened
20 stent for ease of illustration and it is well known in the art that stents preferably have a cylindrical configuration (and which also may be tapered).

Typically, the stent 10 is laser cut from a solid tube. Thus, the stent does not possess discrete individual components. However, for the purposes of description it is beneficial to refer to the stent as being composed of cylindrical rings and
25 connecting links. In one embodiment, it is also beneficial to refer to the individual rings, when viewed in isolation, as being composed of alternating U-shaped portions. Alternatively, the rings may be visualized as being composed of alternating peak and valley portions.

Referring now to FIGS. 5, 6, and 7, in one embodiment, the stent 10 is made up of a plurality of cylindrical rings 30 which extend circumferentially around the stent, and of longitudinal connecting links 31, where at least one connecting link connects each adjacent ring. The stent has an initial delivery diameter 32 as shown in FIG. 5, and an as machined diameter 34 as shown in FIG. 6. The stent further has an expanded diameter as shown in FIG. 7. Each cylindrical ring 30 has a cylindrical ring proximal end 36 and a cylindrical ring distal end 38. Each cylindrical ring 30 defines a cylindrical plane 40 which is a plane defined by the proximal and distal ends of the ring, 36 and 38, and the circumferential extent as the cylindrical ring travels circumferentially around the cylinder. Each cylindrical ring includes a cylindrical outer wall surface 42 which defines the outermost surface of the stent, and a cylindrical inner wall surface 44 which defines the innermost surface of the stent. The cylindrical plane 40 follows the cylindrical outer wall surface. When viewed in isolation, as is shown by the cutaway portions of FIGS. 5, 6, and 7, each cylindrical ring is composed of a plurality of stylized U-shaped portions 46, each of which includes a closed apex 45 and an open end 47 (FIG. 8). Alternatively, the cylindrical rings may be described as comprising a plurality of alternating peaks 45 and valleys 47.

Referring now to FIGS. 8 and 9, a single U-shaped portion 46, as it would appear when the stent 10 is compressed or crimped to its initial delivery diameter, is depicted. The U-shaped element 46 includes a pair of generally S-shaped struts 48, which have respective first ends 49 and second ends 50. The first ends of the struts are joined to form the apex or peak 45 of the U-shaped portion. The second ends curve outwardly to form the open end or valley 47 of the U-shaped portion. Each S-shaped strut is further comprised of an upper portion 52 and a lower portion 54. Joining the upper and lower portions is a stepped transition portion 56. The stepped transition portion allows the lower portion of each strut to slide underneath the upper portion of each preceding, nested U-shaped element in the preceding, nested cylindrical ring 30. Therefore, when the stent 10 is crimped or compressed to its initial delivery diameter, the lower portions of the struts in each cylindrical ring slide underneath the upper

5 multi-porous stent will be positioned so that the larger pores 55 are oriented to the side branch. The guide wire and/or catheter are then removed and the stent remains in position until no longer needed.

Another approach to maintaining patency at the point of bifurcation of the carotid is
10 by deploying a bifurcated stent. The bifurcated stent 80 (Figures 6 B, C & D) can also be made self-expanding from a shape-memory alloy or balloon expandable. The bifurcated stent 80 may be conveniently positioned at the juncture by means of dual guide wires as shown in Figure 6. The pair of guide wires 20 are advanced through the common carotid artery (or other vessel) until they reach the bifurcation point. One guide wire 20 is inserted and
15 advanced into the external carotid artery (or other side branch) whereas the other guide wire 20 projects further into the internal carotid artery (or other vessel). The bifurcated stent 80 is advanced along the guide wires 20 by an over-the-wire catheter 60 or similar device such that when the stent 80 reaches the point of division at the juncture of the internal and external carotid arteries (or other bifurcated vessel), the arms of the bifurcated stent 80 divides. This
20 division of the bifurcated stent 80 can be aided by using two filter/trap/occluders 40 because of the retention force that they may have due to their impinging against the wall of the vessel. This will have a tendency to anchor the wire 20 and keep it from pulling out. This characteristic of the filter/trap/occluder is obviously of benefit elsewhere other than in Figure 6 and even outside the scope of the present invention. One arm of the bifurcated stent will
25 project into the internal carotid artery and the other arm into the external carotid artery with the main portion of the stent remaining in the common and internal carotid arteries (or other bifurcated vessels). This is shown clearly in Figures 6B and 6C. After the stent is warmed in the case of a self-expanding stent or stent-graft (or otherwise enlarged) the guide wires 20 may be removed and the stent remains in position as shown in Figure 6D.

struts which also tends to improve retention of the stent on the balloon.

Referring now to FIG. 10, for the purpose of illustration only, the stent 10 is shown in its as manufactured state as a flat pattern so that the pattern of rings 30 and links 31 may be more clearly viewed. In the as manufactured state, the U-shaped portions 46 and the struts 48 are relatively straight and angular in appearance in contrast to the generally curved appearance these portions have in their compressed initial delivery state. In the exemplary embodiment shown in FIG. 10, each cylindrical ring is connected to each adjacent ring by three rows of longitudinal connecting links which are equally spaced at 120 degree intervals around the circumference of the stent. In alternative embodiments, the connecting links may be radially offset from one adjacent ring to the next.

Again, it is to be emphasized that the above described rings, U-shaped portions, struts, and connecting links are for purposes of clarity of description only. The stent 10 is machined as a unitary structure and therefore does not actually contain any discrete components.

Alternative embodiments of the stent of the present invention are shown in FIGS. 11A and 11B, 12A and 12B, 13A and 13B, 14A and 14B, and 15A and 15B. The stents shown in FIGS. 11A-14B represent stent patterns that are well known and which are adapted to incorporate the overlap features of the present invention as described. Importantly, the struts of these embodiments may overlap in any manner to achieve the desired low profile delivery diameter, high gripping force on the catheter, and enhanced expanded diameter. The stent shown in FIGS. 11A and 11B is sold under the tradename GFX and is manufactured by AVE Medtronic of Santa Rosa, California. The stent shown in FIGS. 12A and 12B is sold under the tradename AVE S670 and is manufactured by AVE Medtronic of Santa Rosa, California. The stent shown in FIGS. 13A and 13B is sold under the tradename NIR by Boston Scientific Corporation of Natick, Massachusetts. The stent shown in FIGS. 14A and 14B is sold under the tradename BX VELOCITY and is manufactured by Cordis Corporation, a division of Johnson & Johnson Company, Warren, New Jersey. The stent shown in FIGS. 15A

and 15B is sold under the tradename DUET and is manufactured by Advanced Cardiovascular Systems, Inc., of Santa Clara, California.

The stent 10 may be produced by several methods including electro-discharge machining and chemical etching. However, the preferred method is to laser
5 cut a thin-walled tubular member, such as a hypotube. In this procedure, a computer controlled laser cuts away portions of the hypotube following a pre-programmed template to form the desired strut pattern. Methods and equipment for laser machining small diameter tubing are known in the art.

The laser machining process leaves a thin heat effected zone around the
10 pattern cut in the drawn tube and a resulting surface finish that is somewhat coarse and unsuitable for implantation in living tissue. The surface roughness of stents in the "as machined" condition is on the order of about 50-100 microns, while stents suitable for implantation within a blood vessel typically require a surface roughness of about .2 to .05 microns.

15 To achieve the required surface finish, stents are typically descaled and electro-polished. One method of descaling involves immersing the stents in an alkaline cleaner and ultrasonically agitating the stents for a selected period of time. Another method involves bead blasting stents with fine glass beads. There are other procedures for descaling are well known to those skilled in the art.

20 The principles of electro-polishing are also known in the art. Typically, an item to be electro-polished is immersed in an electrolyte which comprises an aqueous acidic solution. The item to be polished is made a positive electrode (anode) and a negative electrode (cathode) is placed in close proximity to the anode. The anode and cathode are connected to a source of electric potential difference with the electrolyte
25 completing the circuit between anode and cathode. Upon the passage of electric current through the electrolyte, metal is dissolved from the anode surface with protrusions being dissolved faster than depressions, thereby producing a smooth surface. The rate of material removal in an electro-polishing process is primarily a function of the electrolyte chosen and the current density in the electrolyte fluid.

Typically, with stainless steel stents, a final step in the electro-polishing process involves passivation of the newly polished surface. After removal from the electrolyte solution and rinsing with water, residual anions of the acid used in the electrolyte remain in contact with the polished surface. The presence of such surface
5 anions leads to deterioration of the newly polished surface when the residual anions come into contact with calcium and magnesium ions which are commonly found in non-deionized water (ordinary tap water). To prevent surface deterioration, newly polished stents are immersed in a passivation bath which typically consists of a solution of nitric acid, deionized water, and sodium dichromate. The passivation bath neutralizes the
10 residual anions and leaves a protective, corrosion resistant, strongly adherent, transparent, chromium dioxide coating on the newly polished surface.

With nickel-titanium alloy stents, however, the passivation step is generally not required. Nickel-titanium alloys tend to form a titanium oxide rich surface layer during initial heat treatment of the alloy which renders the alloy relatively
15 impervious to the corrosive effects of any residual anions that may be left on the stent surface after electro-polishing.

The tubing used to make the stent 10 may be made of any bio-compatible spring steel or shape memory alloy. The 300 series stainless steel alloys are well suited to this application with type 316L stainless steel per ASTM F138-92 or ASTM F139-92
20 grade 2 being preferred. Of the shape memory or super-elastic alloys, Nitinol, a 55% nickel - 45% titanium alloy is preferred. Other shape memory alloys such as Ni-Ti-X (X being V, Co, Cu, Fe) ternary alloys, Cu-Al-Ni ternary alloys and Cu-Zn-Al ternary alloys are also suitable.

Typically, suitably sized tubing for making the stent 10 will have an
25 outside diameter of about 0.020 - 0.060 inches, with a wall thickness of about 0.003 - 0.006 inches. However, tubing size will vary depending upon the application. It is preferred that the stent be machined from seamless tubing. However, tubing formed by rolling flat, sheet stock into a cylinder with welded longitudinal edges is also suitable, as is rolled sheet stock which has been drawn through a circular die.

It will be appreciated that a new stent having an overlapping strut pattern has been presented. The overlapping strut pattern allows the stent to crimped to a smaller initial delivery profile than has heretofore been possible. The lower profile allows physicians to reach and treat lesions in smaller and more tortuous vessels than
5 may be treated with conventional stents. In addition, the overlapping strut pattern allows balloon material to be caught between the sliding struts and thereby improves stent security on an inflation balloon.

While only the presently preferred embodiments have been described in detail, as will be apparent to those skilled in the art, modifications and improvements
10 may be made to the device and method disclosed herein without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED:

1. An intravascular stent for use in a body lumen, comprising:
an elongated tubular body having a plurality of struts forming a
stent pattern;
5 the tubular member having a first diameter for navigating the body
lumen and a second expanded diameter for implanting in the body lumen;
at least some of the struts are overlapping and some of the struts
are non-overlapping when the tubular member is in the first diameter.
2. The stent of claim 1, wherein the overlapping struts expand and
become non-overlapping struts in the second expanded diameter configuration.
3. The stent of claim 1, wherein the stent pattern has a plurality of
cylindrical rings that are interconnected.
4. The stent of claim 3, wherein the cylindrical rings are connected
by at least one connector member.
5. The stent of claim 4, wherein the connector member is a link.
6. The stent of claim 3, wherein at least some of the cylindrical rings
have overlapping struts.
7. The stent of claim 4, wherein at least some of the connector
members have overlapping struts with cylindrical ring struts.
8. The stent of claim 1, wherein the overlapping struts define an inner
diameter portion and an outer diameter portion.
9. An intravascular stent for use in a body lumen,
comprising:
a plurality of nested cylindrical rings having an initial delivery
diameter and an expanded deployed diameter, the rings being formed from a plurality
5 of alternating U-shaped portions;
the U-shaped portions of each cylindrical ring overlap the U-
shaped portions of each adjacent cylindrical ring;

each cylindrical ring having a proximal end and a distal end and a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring; and

the cylindrical rings being interconnected to form the stent,
5 wherein at least one connecting link attaches each cylindrical ring to an adjacent cylindrical ring.

10. The stent of claim 9, wherein each U-shaped element is formed from struts, the struts having first ends and second ends and being joined at the first ends to form an apex, and curving outwardly therefrom to form an open end of the U-shaped portion.

11. The stent of claim 10, wherein each strut has a stepped transition portion which divides each strut into an upper portion and a lower portion.

12. The stent of claim 11, wherein the lower portions of the struts in each cylindrical ring slide underneath the upper portions of the struts in an adjacent cylindrical ring, when the stent is compressed to its delivery diameter.

13. The stent of claim 10, wherein each strut has a generally S-shaped configuration.

14. The stent of claim 10, wherein the apexes of each U-shaped element in each cylindrical ring are circumferentially offset from the apexes of each U-shaped element in each adjacent ring.

15. The stent of claim 10, wherein the nested cylindrical rings are nested such that the apexes of each ring are centered approximately midway within the U-shaped portions of each adjacent ring.

16. The stent of claim 9, wherein the stent is formed from a tube.

17. The stent of claim 9, wherein the stent is formed from a metal alloy.

18. The stent of claim 9, wherein the stent is formed from stainless steel.

19. The stent of claim 9, wherein the stent is formed from a shape memory alloy.

20. The stent of claim 9, wherein the stent is formed from a superelastic alloy.

21. The stent of claim 9, wherein the stent is formed from a polymer.

22. A stent for use in a body lumen, comprising:

a plurality of nested cylindrical rings interconnected to form the stent, each cylindrical ring having an initial delivery diameter and an expanded deployed diameter;

5 each cylindrical ring having a plurality of peaks and valleys, the valleys of one cylindrical ring being circumferentially offset from the valleys of an adjacent cylindrical ring, wherein the valleys of one cylindrical ring overlap the valleys of an adjacent cylindrical ring; and

at least one connecting link attaching each cylindrical ring to an adjacent cylindrical ring, the connecting link being positioned substantially within one of the valleys and attaching the valley to an adjacent peak.

23. The stent of claim 22, wherein the cylindrical rings are nested such that the peaks of one cylindrical ring are centered approximately midway within the valleys of an adjacent cylindrical ring.

24. The stent of claim 22, wherein each peak and valley is formed from struts, the struts having first ends and second ends and being joined at the first ends to form a peak and being separated at the second ends to form a valley therebetween.

25. The stent of claim 24, wherein each strut has a stepped transition portion which divides each strut into an upper portion and a lower portion.

26. The stent of claim 24, wherein the lower portions of the struts in each cylindrical ring slide underneath the upper portions of the struts in a preceding cylindrical ring, when the stent is compressed to its delivery diameter.

27. The stent of claim 24, wherein each strut has a generally S-shaped configuration.

28. The stent of claim 22, wherein the stent is formed from a tube.

29. The stent of claim 22, wherein the stent is formed from a metal alloy.

30. The stent of claim 22, wherein the stent is formed from stainless steel.

31. The stent of claim 22, wherein the stent is formed from a shape memory alloy.

32. The stent of claim 22, wherein the stent is formed from a superelastic alloy.

33. The stent of claim 22, wherein the stent is formed from a polymer.

34. A stent for use in a body lumen, comprising:

a plurality of nested cylindrical rings interconnected to form the stent, each cylindrical ring having an initial delivery diameter and an expanded deployed diameter;

5 each cylindrical ring having a plurality of peaks and valleys;

means for causing the valleys of each cylindrical ring to overlap the valleys of each adjacent cylindrical ring when the stent is compressed to its initial delivery diameter; and

10 means for connecting each cylindrical ring to an adjacent cylindrical ring.

FIG. 1

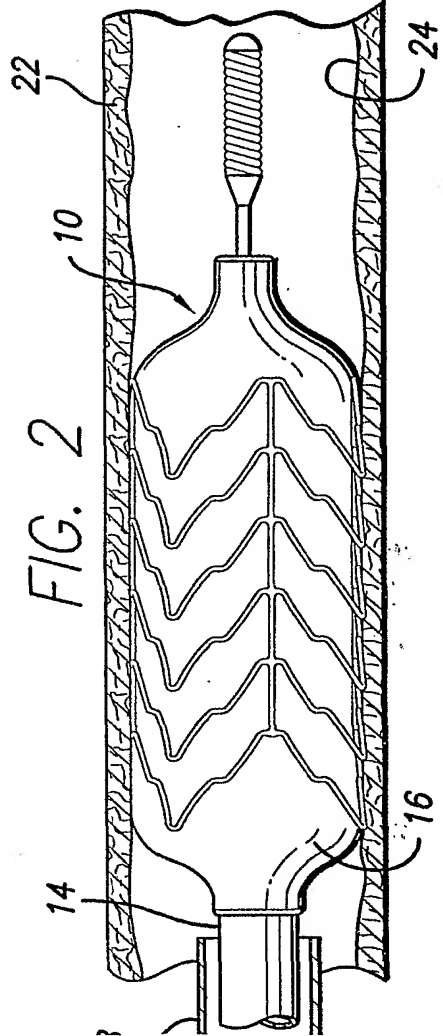
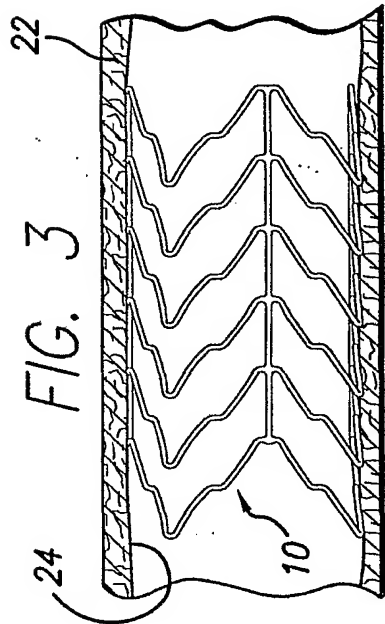
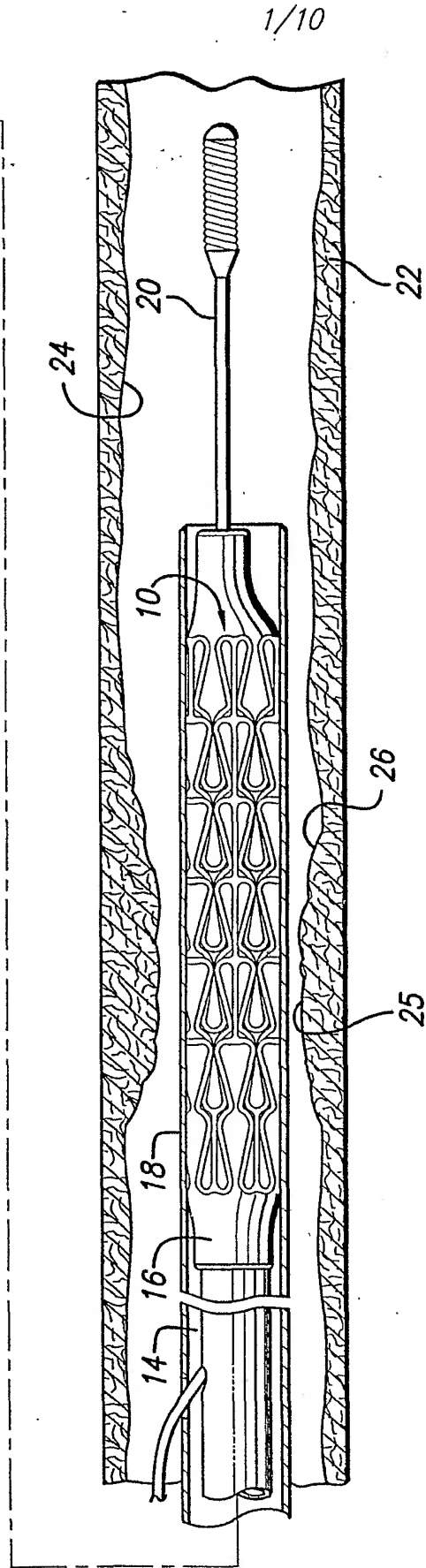
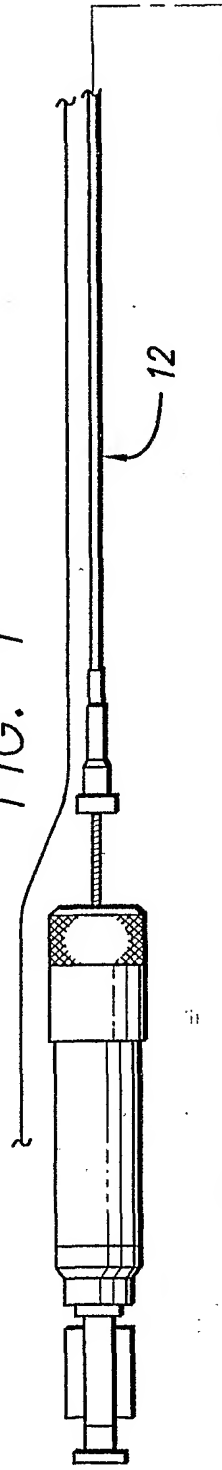


FIG. 4A

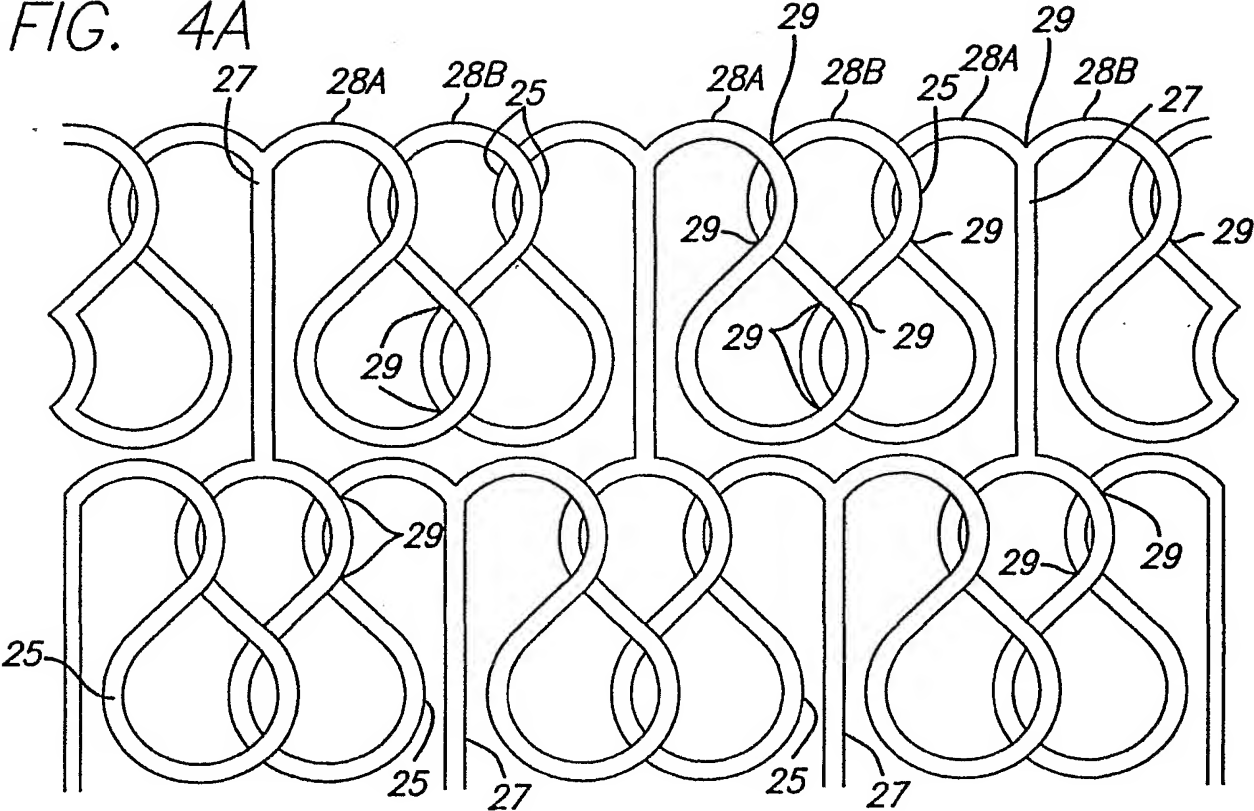
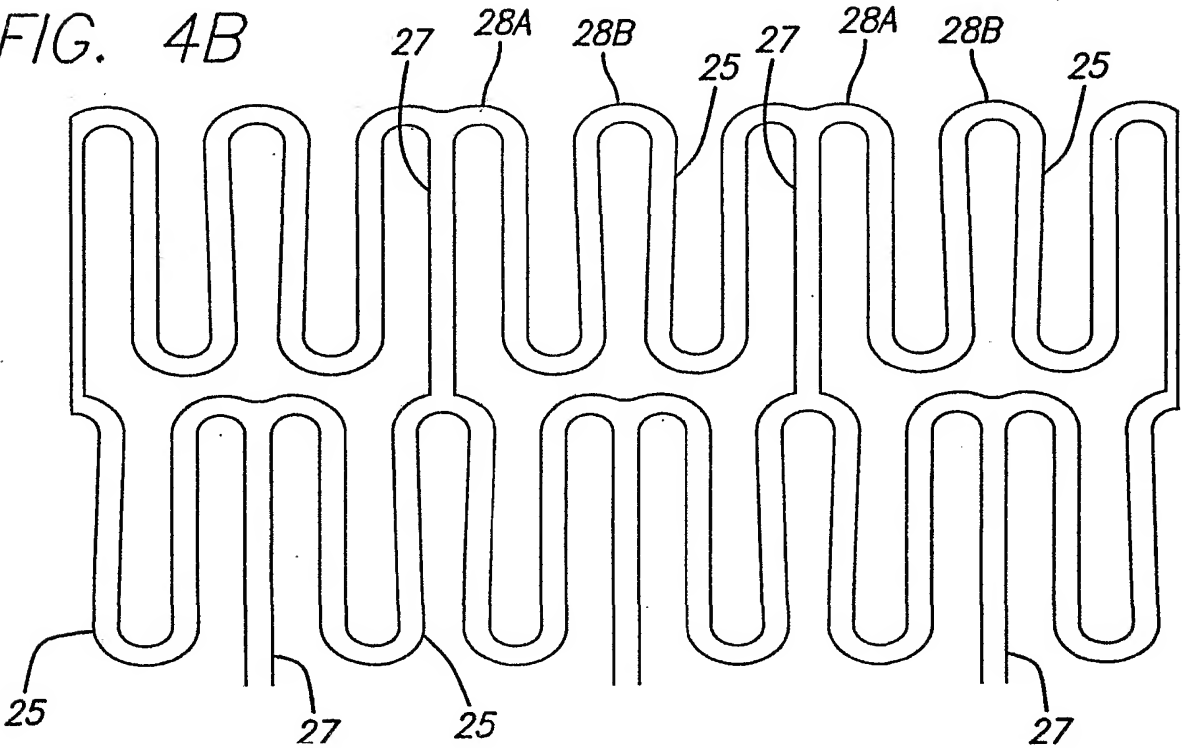
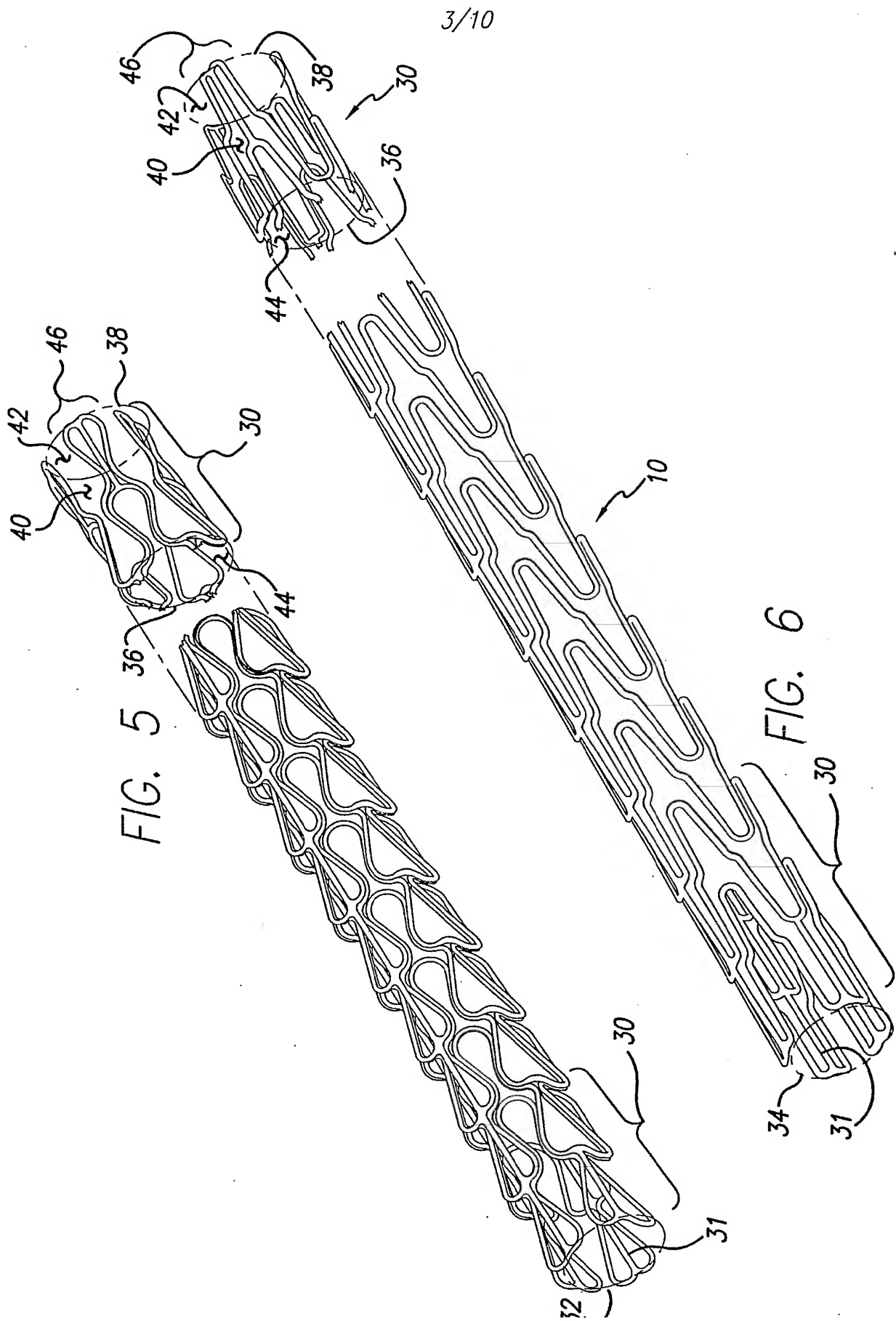
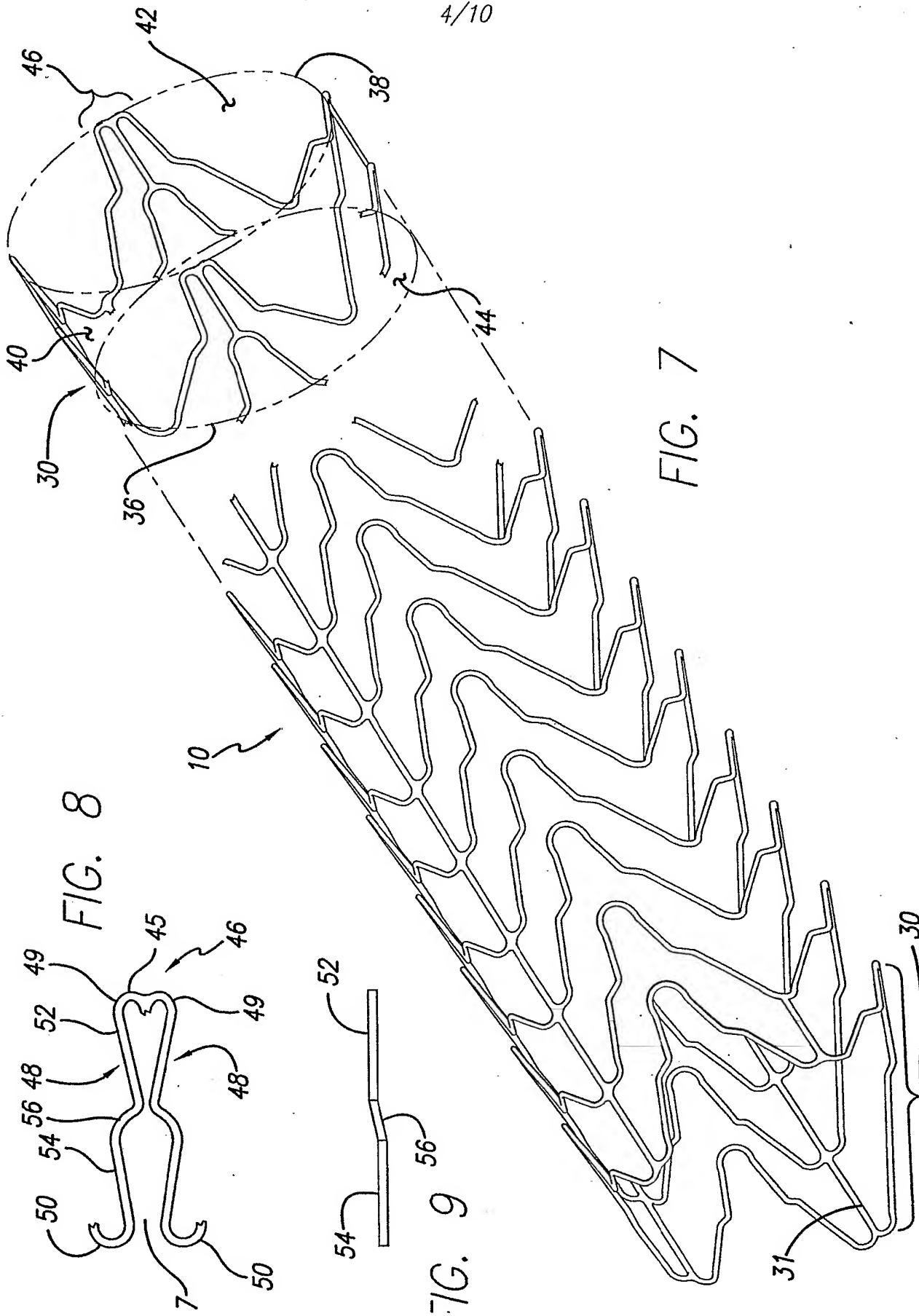


FIG. 4B





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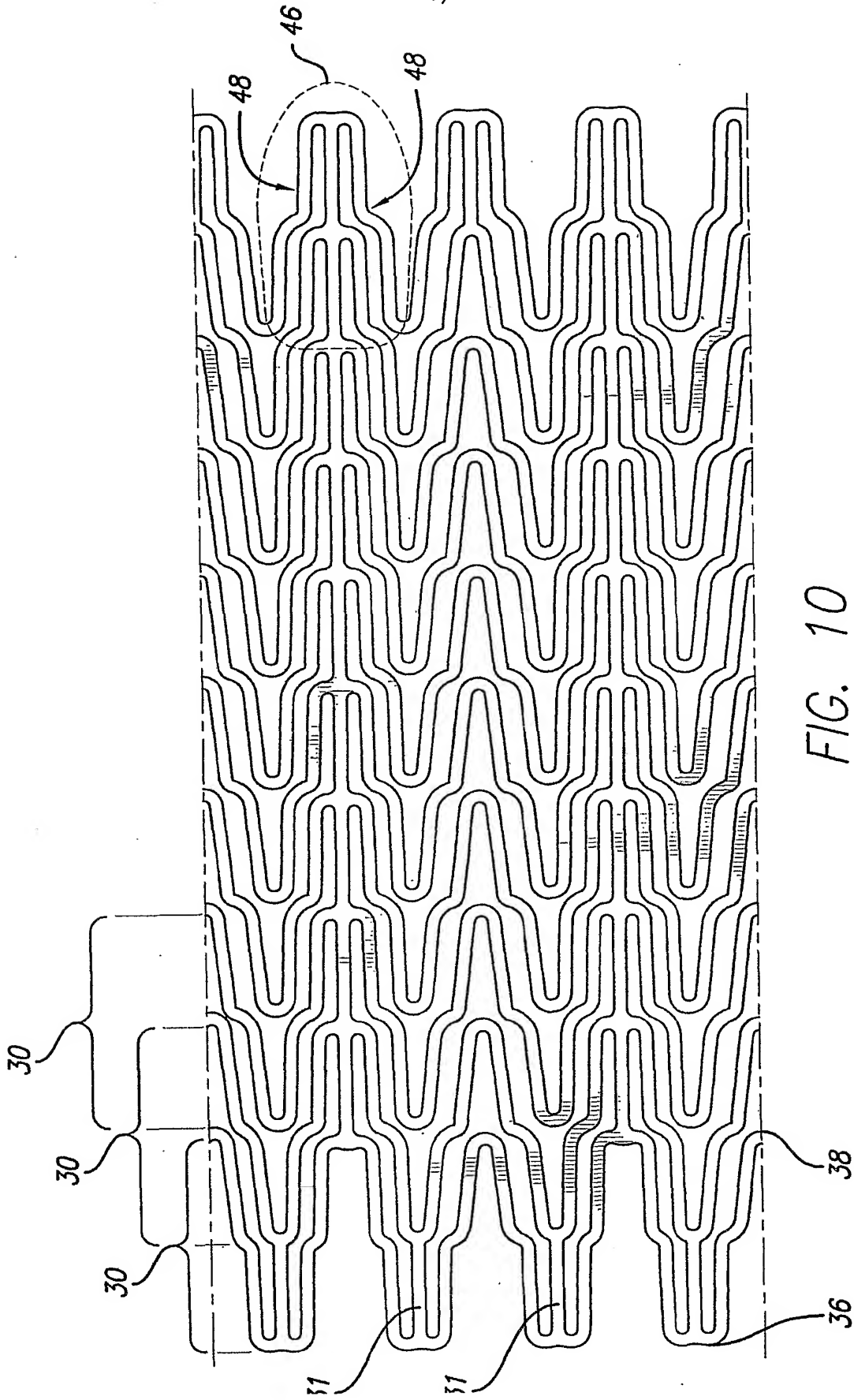


FIG. 11A

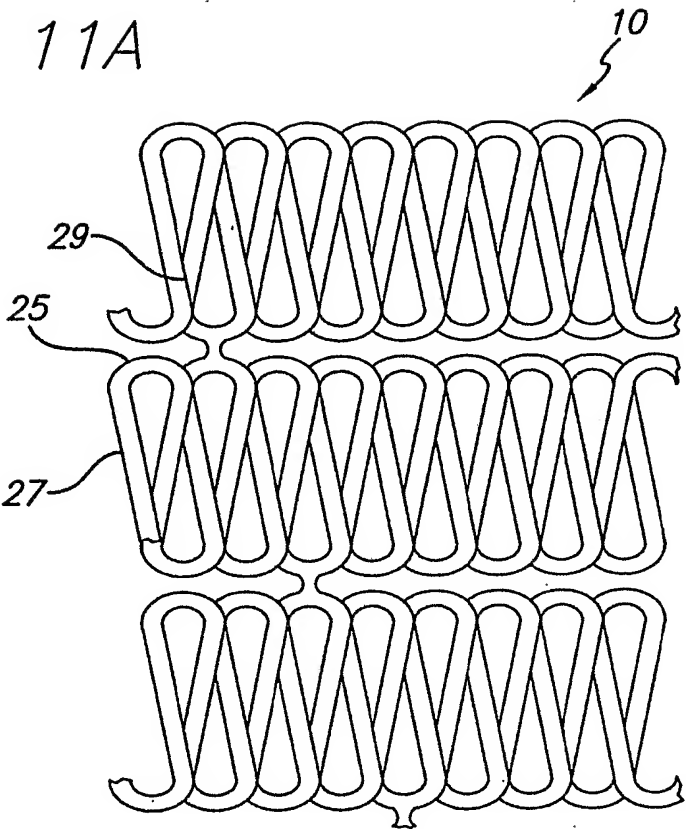


FIG. 11B

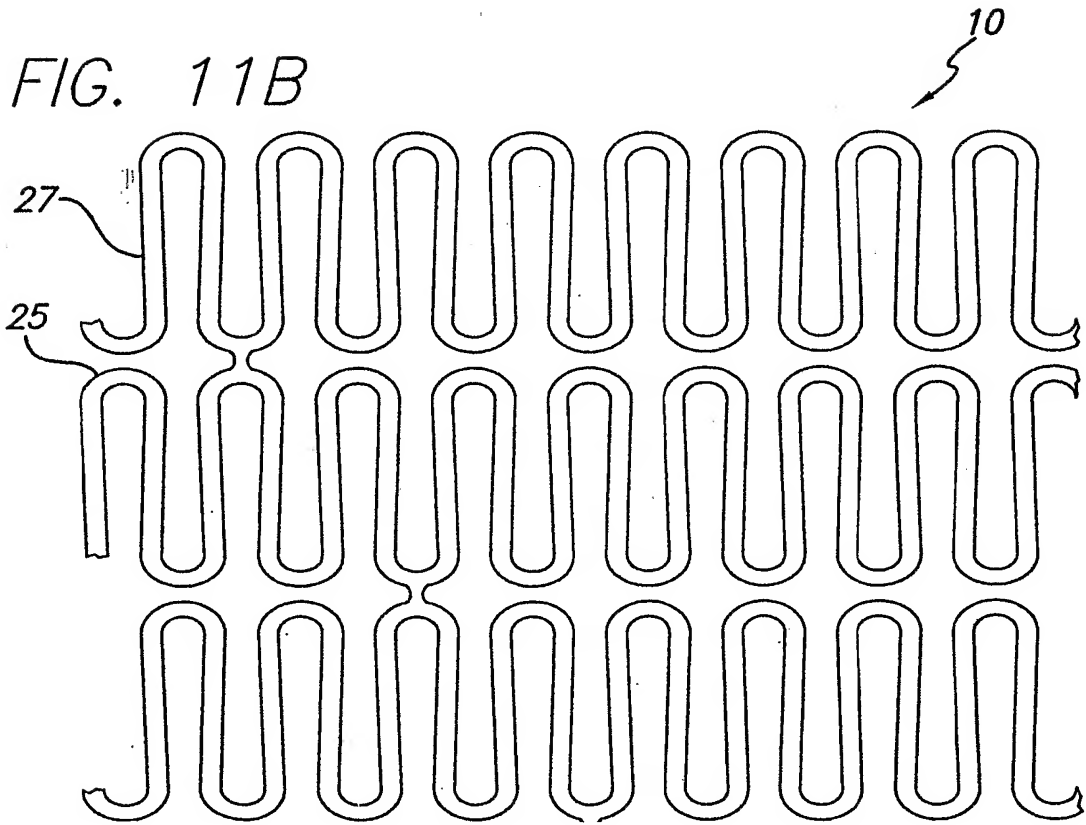


FIG. 12A

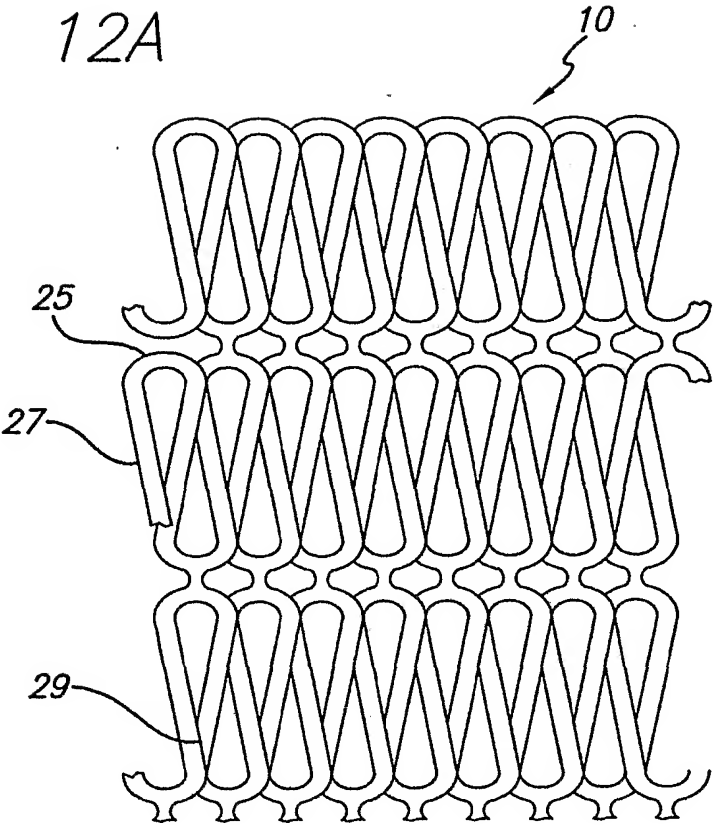
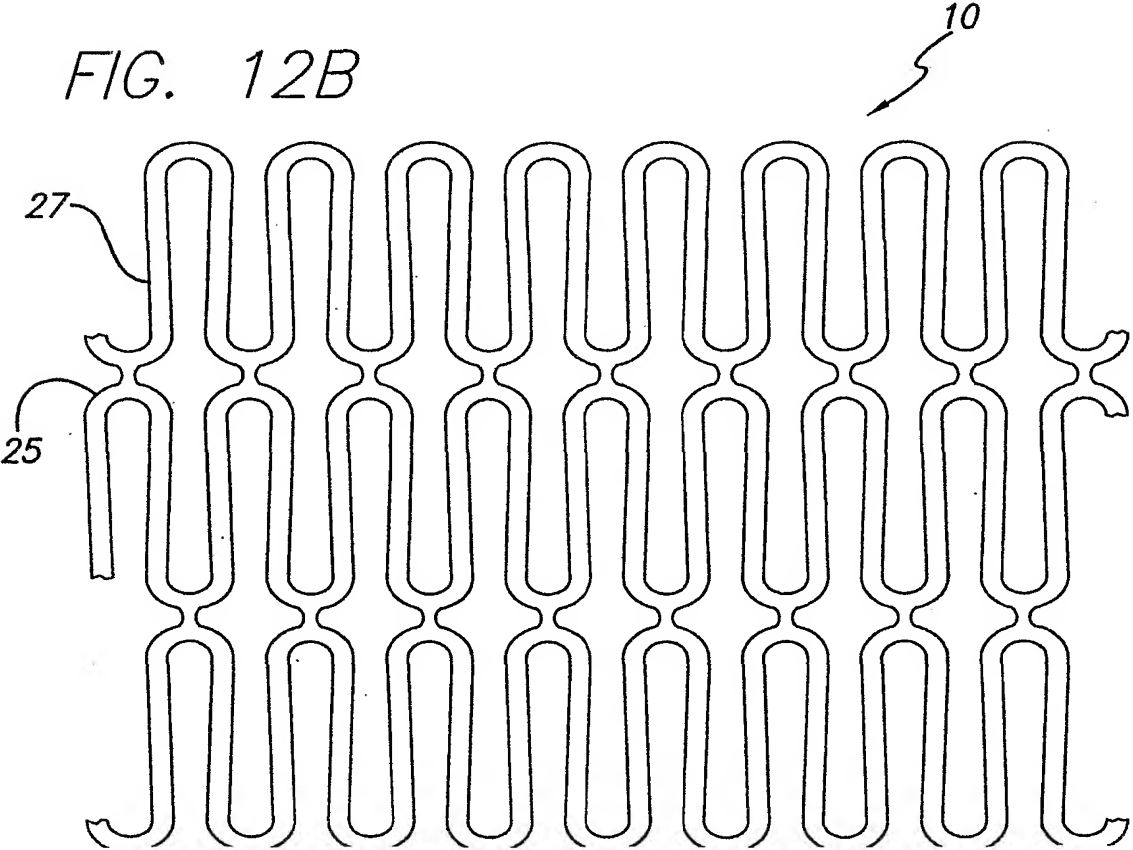


FIG. 12B



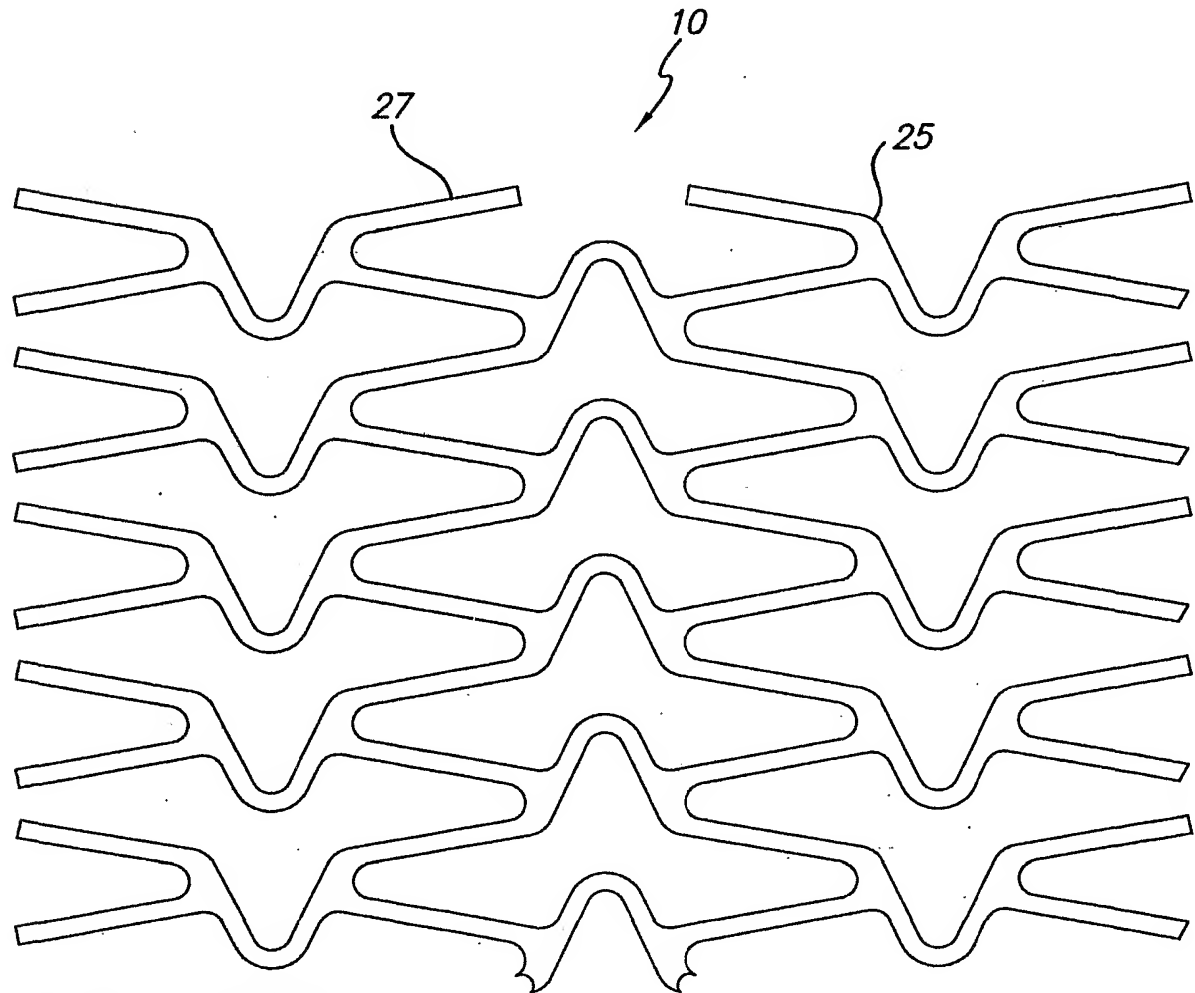
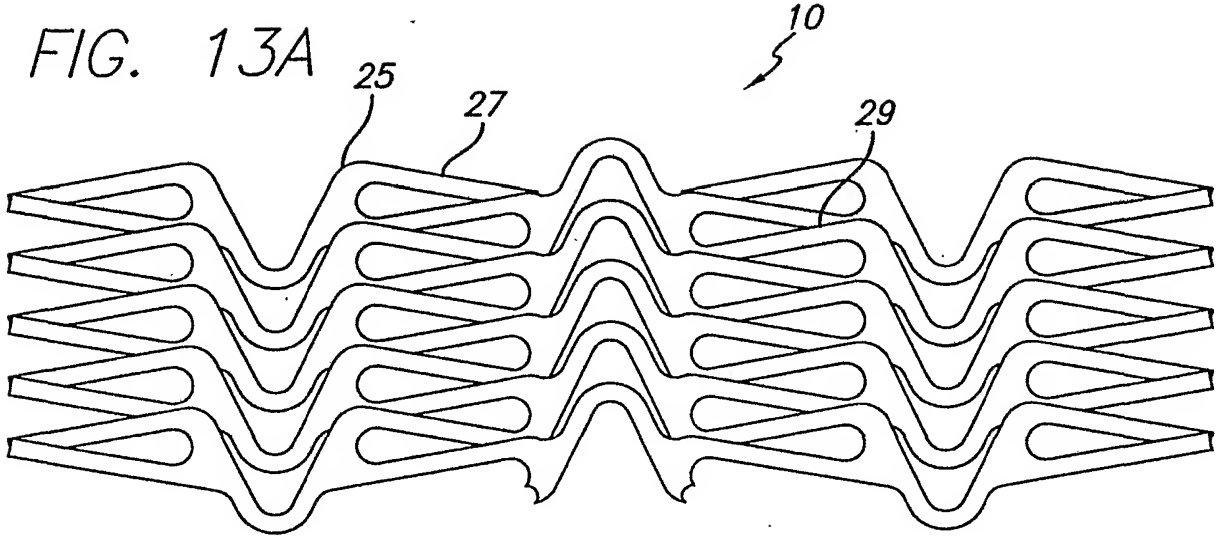


FIG 1.3B

FIG. 14A

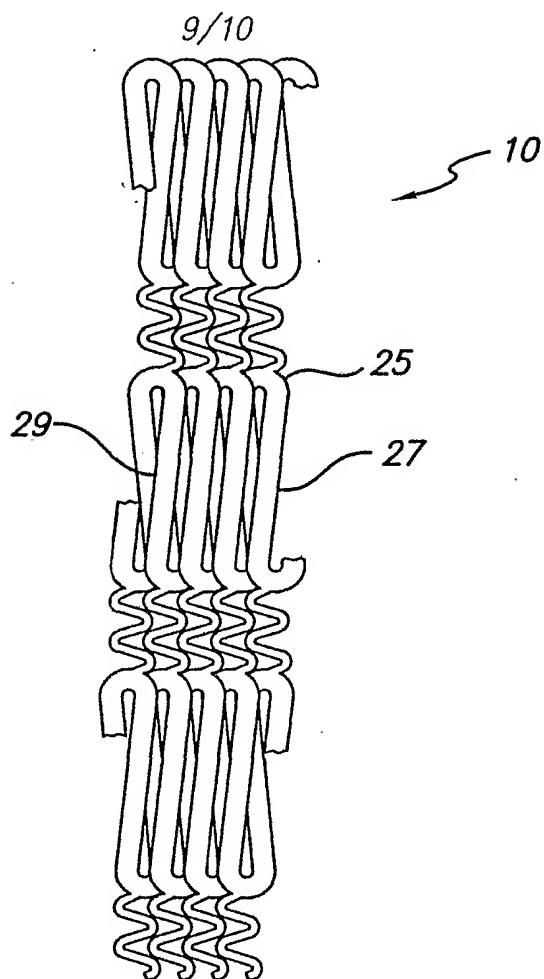
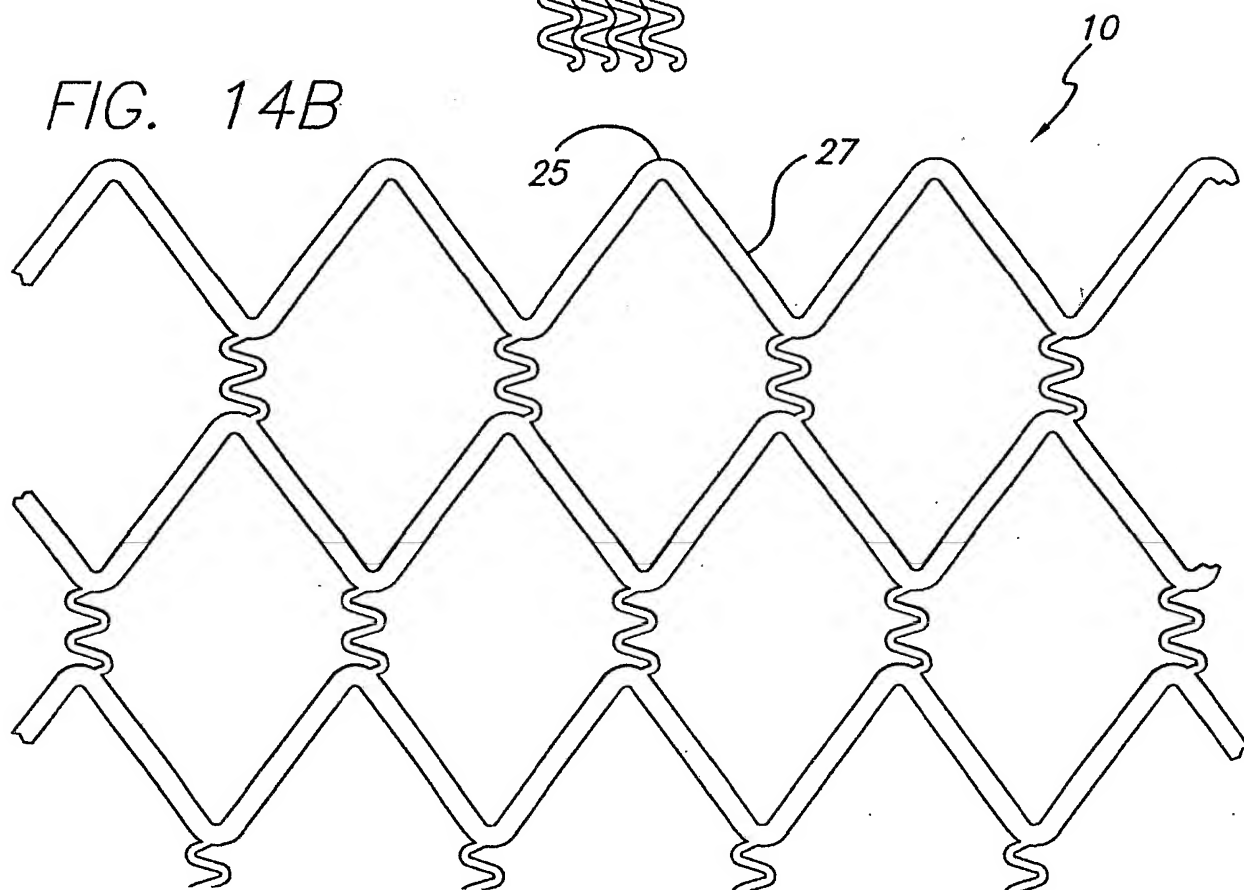


FIG. 14B



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